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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,530	07/24/2000	Richard Sackler	200.93185C2C	5659
23280 7590 01/26/2007 DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			EXAMINER CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/624,530

Applicant(s)

SACKLER ET AL.

Examiner

Yong S. Chong

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-8, 13-16 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8, 13-16, 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2006 has been entered.

Claim(s) 1-5, 9-12, 17-23 have been cancelled. Claim(s) 25-30 have been added. Claim(s) 6-8, 13-16, 24-30 are pending. Claim(s) 6, 24 have been amended. Claim(s) 6-8, 13-16, 24-30 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below for Applicant's convenience.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 13-16, 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al. (USPN 4844909).

Goldie et al. teaches a solid release oral dosage form, the dosage form comprising a therapeutically effective amount of hydromorphone or salt thereof in a matrix wherein the dissolution rate in vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 mL aqueous buffer at pH 1.6 and 7.2 and at 37 °C overlaps with those as instantly claimed (Abstract). Peak plasma level is achieved between 2 and 4 hours (Abstract). The amount of hydromorphone released at a pH of 1.6 is less than 10% than that released at any pH up to 7.2 (col. 1, lines 29-35). Therapeutic levels of hydromorphone are maintained in vivo for *at least* 12 hours (col. 2, lines 3-10). Compositions wherein peak plasma levels are achieved between 4 and 8 hours are also taught to provide at least 12 hours of therapeutic effect (col. 2, lines 11-23). Gums, cellulose ethers, acrylic resins, C8-C50 long chain hydrocarbons, fatty acids, fatty alcohols, mineral oils, vegetable oils, waxes and polyalkylene glycols are disclosed as matrix materials (col. 2, line 47-col. 3, line 6). Dosage forms comprising between 2 and 40 mg of hydromorphone are taught (col. 2, lines 41-46). Blood plasma levels are exemplified as 1.0 ng/mL and 2.1 ng/mL at 12 hours and 1.1 ng/mL and 1.4 ng/mL at 24 hours (Tables 5 and 6).

Goldie et al. does not specifically disclose a dosage form wherein the peak plasma level is obtained between 4.42 and 8 hours after administration of the dosage form.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a dosage form wherein the peak plasma level is between 4.42 and 8 hours after administration of the dosage form because it is well known in the

pharmaceutical art to have produced a formulation that gives a peak plasma level of the drug between 4 to 8 hours after administration. One would have been motivated to prepare a dosage form, which achieved maximum plasma levels between 4.42 to 8 hours because of an expectation of similar success in preparing a dosage form, which achieved therapeutic effects for at least 12 hours.

Furthermore, even if between 2 and 4 hours is not considered inclusive of 4 hours, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a dosage form with a the peak plasma level obtained between 4 and 8 hours after administration of the dosage form because Goldie et al. teaches that dosage forms achieving a peak plasma level between 2 and 4 hours are, surprisingly, interchangeable with dosage forms that achieve peak plasma levels between about 4 and 8 hours after administration. Both dosage forms are taught to achieve the desired effect. Namely, both are taught to achieve a therapeutic effect for at least 12 hours. Accordingly, one would have been motivated to administer a dosage form that achieves a peak plasma level between 4 and 8 hours after administration because of an expectation of administering a dosage form suitable for achieving a therapeutic effect for at least 12 hours.

It is noted that the exemplified clinical studies teach plasma levels at 24 hours wherein the amount present is a therapeutically effective amount because (1) the dosage form is taught to be therapeutically effective for at least 12 hours and the plasma levels at 24 hours are not significantly different than the plasma levels at 12

hours; and (2) the plasma levels are within the scope of the plasma levels as instantly claimed in claim 20.

### ***Response to Arguments***

Applicant argues that the amended range of 4.42 to 8 hours does not overlap with, and is neither taught nor suggested by, the range in Goldie of 2 to 4 hours.

This is not persuasive because, as admitted by the Applicant, Goldie teaches the range of 2 to 4 hours. Therefore, it is obvious to one of ordinary skill in the art to have optimized the range of peak plasma level.

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

Applicant argues that the range of 4 to 8 hours in Goldie refers to a formulation of a "drug" and is not specific to hydromorphone. Applicant also argues that the Goldie reference makes no mention of the plasma level at 24 hours, which would be considered to be therapeutically effective.

This is not persuasive because the 4 to 8 hour range disclosed by Goldie refers to a formulation in the known pharmaceutical art to give a peak plasma drug level. Certainly, the disclosed hydromorphone (later on in the same paragraph) fits this criterion as being a drug known in the pharmaceutical arts for giving a peak plasma drug level in a controlled drug dosage form. Furthermore, the paragraph in Goldie reads "at least a 12 hour therapeutic effect," which the Examiner interprets as meeting n the claimed 24 hour effect. Again, it is noted that Goldie discloses that it is well known in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between 4 to 8 hours after administration.

### ***Conclusion***

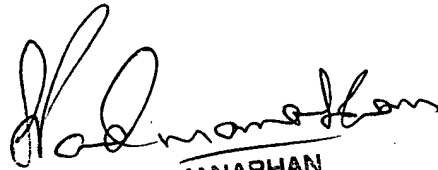
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER